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| APPLICATION NO.  | FILING DATE                       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------------------|----------------------|---------------------|------------------|
| 10/560,389   | 12/13/2005                        | J Michael Palmowski  | 0380-P03220US1      | 2535             |
|  | 7590 01/22/200<br>MAN HERREII & S | EXAMINER .           |                     |                  |
| DANN, DORFMAN, HERRELL & SKILLMAN<br>1601 MARKET STREET<br>SUITE 2400<br>PHILADELPHIA, PA 19103-2307 |                                   |                      | BLUMEL, BENJAMIN P  |                  |
|  |                                   |                      | ART UNIT            | PAPER NUMBER     |
|  | <b>,</b>                          |                      | 1648                |                  |
|  |                                   |                      |                     |                  |
|  |                                   |                      | MAIL DATE           | DELIVERY MODE    |
|  |                                   |                      | 01/22/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s)  |  |  |  |  |
|--|---|---|--|--|--|--|
|  | 10/560,389  | PALMOWSKI ET AL.  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit  |  |  |  |  |
|  | Benjamin P. Blumel  | 1648  |  |  |  |  |
| The MAILING DATE of this communication app   | ears on the cover sheet with  | the correspondence address  |  |  |  |  |
| Period for Reply   | / IC CET TO EVDIDE 4 MON  | NITU(S) OD THIDTY (30) DAVS   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICA 36(a). In no event, however, may a reply viil apply and will expire SIX (6) MONTH: cause the application to become ABAN | ATION. y be timely filed S from the mailing date of this communication. IDONED (35 U.S.C. § 133). |  |  |  |  |
| Status   |   |   |  |  |  |  |
| 1) Responsive to communication(s) filed on 12 De   | ecember 2005.   |   |  |  |  |  |
| ,  | ·   |   |  |  |  |  |
|  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is                               |   |  |  |  |  |
| closed in accordance with the practice under E   | x parte Quayle, 1935 C.D. 1   | 1, 453 O.G. 213.  |  |  |  |  |
| Disposition of Claims  |   |   |  |  |  |  |
| 4) Claim(s) 1-30 is/are pending in the application.  |   |   |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |   |  |  |  |  |
| 5) Claim(s) is/are allowed.  | ,   |   |  |  |  |  |
|  | Claim(s) is/are rejected.   |   |  |  |  |  |
| 7) Claim(s) is/are objected to.  8) Claim(s) <u>1-30</u> are subject to restriction and/or e   | 7) Claim(s) is/are objected to.   |   |  |  |  |  |
| Old Claim(s) 1-50 are subject to restriction and/or e  | siection requirement.   | ·   |  |  |  |  |
| Application Papers   |   |   |  |  |  |  |
| 9) The specification is objected to by the Examine   | r.  |   |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ acco  |   |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |   |  |  |  |  |
|  | amilier. Note the attached c  | Since Action of formal 10 102.  |  |  |  |  |
| Priority under 35 U.S.C. § 119   | •   |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |   |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |   |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |   |  |  |  |  |
| <ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>  |   |   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  |   |   |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |   |  |  |  |  |
| ,  |   |   |  |  |  |  |
| Attachment(s)  |   |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date   |   |   |  |  |  |  |
| Notice of Draitsperson's Patent Drawing Review (PTO-946)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date   |   | rmal Patent Application   |  |  |  |  |

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#### DETAILED ACTION

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, drawn to a method of inducing an immune response through a prime-boost regimen.

Group II, claim(s) 19-30, drawn to a prime-boost kit of stimulating an immune response.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claims are directed to a method of using a prime-boost kit in inducing an immune response through a prime-boost regimen. However, because Tellier et al. (AIDS, 1998) teach a prime-boost regimen utilizing recombinant canarypox (prime) and feline immunodeficiency virus (boost) for inducing immune responses in cats, no special technical feature exists for groups I-II as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Note that PCT Rule 13 does not provide for multiple products or methods within a single application. Because the shared technical feature of Groups I-II is not a special technical feature, unity of invention is lacking.

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## Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

No matter which invention is elected, a specific species must also be elected from each group listed below.

- A. A specific antigen (i.e., lentiviral vector or APC containing lentivirus) as stated in claims 1 and 19.
- **B.** A specific antigen as stated in claims 2 and 20.
  - i. If applicants elect iii), a specific virus must also be elected from claims 3, 4, 21 and 22.
- C. A specific prime-boost regimen as stated in claims 5, 9-12, 23 and 27-30.

If applicants elect invention I, a specific species must also be elected from the group listed below.

**D.** A specific first immunogen as stated in claims 14 and 16-18. The species elected in group **C.** must correspond with the elected species from group **D.**, (i.e., if claims 6 and 24 are elected from group **C.**, so should claim 17 from group **D.**).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

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argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

- A. Claims 1 and 19 require a specific antigen, all other claims are generic.
- B. Claims 2 and 20 require a specific antigen, all other claims are generic.
  - i. Claims 3, 4, 21 and 22 require a specific virus, all other claims are generic.
- C. Claims 5, 9-12, 23 and 27-30 require a specific prime-boost regimen, all other claims are generic.
- **D.** Claims 14 and 16-18 require a specific first immunogen, all other claims are generic.

The following claim(s) are generic: all claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The antigens, viruses, prime-boost regimens and first immunogens are different based on their physical, chemical and functional properties (i.e., pox viruses and lentiviruses have different nucleic acid genomes, a lentivirus and an APC containing a lentivirus are different entities, etc.).

## Summary

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin P Blumel/ Examiner Art Unit 1648

/Bruce Campell/ Supervisory Patent Examiner Art Unit 1648